



## PHARMACEUTICAL EHS COUNSEL ROUNDTABLE

Wednesday March 1, 2017

Beveridge & Diamond, P.C., 1350 I Street, NW, 7<sup>th</sup> Floor, Washington, DC

Call-in number for those participating by teleconference: 1-877-688-0100; passcode: 202-789-6022

### AGENDA

- 9:30 a.m. – 10:00 a.m.      Coffee and Continental Breakfast**
- 10:00 a.m. – 10:15 a.m.      Welcome and Introductions**
- Review Antitrust Guidelines
  - Meeting Agenda
  - Spring 2016 Meeting Report
- Betsy DuSold, *Eli Lilly***  
**Alan Horowitz, *AstraZeneca***
- 10:15 a.m. – 10:45 a.m.      EPA RCRA Rulemakings Impacting the Management of Pharmaceutical Wastes**
- Final Hazardous Waste Generator Rule
  - Prospects for a Future Rule on Hazardous Waste Pharmaceuticals
  - Reverse Distribution Centers
- Aaron Goldberg, *Beveridge & Diamond, P.C.***
- 10:45 a.m. – 11:15 a.m.      Global PIE Update**
- Expected EU PIE Strategy
  - Recent Initiatives Addressing AMR
  - EPR Measures Targeting Unused Medicines and Devices
  - SAICM Work on Persistent Pharmaceutical Pollutants
- Paul Hagen, *Beveridge & Diamond, P.C.***
- 11:15 a.m. – 12:30 p.m.      Congressional, Executive and Judicial Activities in the Trump Era**
- Congressional Review and Legislative Reforms
  - Confirmation of Cabinet Level Officials
  - Executive Orders and Presidential Memoranda

- Changes at EPA – New Regulatory Dynamics
- Neil Gorsuch Nomination

**David Friedland**, *Beveridge & Diamond, P.C.*

**Stacey J. Sublett**, *Beveridge & Diamond, P.C. (former Special Counsel, Office of General Counsel, US EPA)*

**12:30 p.m. – 1:45 p.m.**

**Environmental Law and Policy Under the Trump Administration – Roundtable Discussion of Expected Impacts on the Pharmaceutical Sector**

- Opportunities for Regulatory Reform
- Increased State and Local Initiatives
- Pharmaceuticals in the Environment
- Likely Citizen Suit Challenges (Rules and Enforcement)
- Others?

**Alan Horowitz**, *AstraZeneca* (Facilitator)

**All Participants**

**1:45 p.m. – 2:30 p.m.**

**New Developments in Federal Regulation of Biotechnology Products**

- APHIS Proposals to Revise Regulation of GE Organisms and Plant Pests (issued on January 19, 2017)
- FDA Proposals to Revise Guidance on Genome-Edited Animals and Plants, and Mosquito-Related Products (issued on January 18, 2017)
- APHIS, FDA, and EPA Update to the Federal Biotechnology Regulatory Framework, and Implications for Genetically Modified Plants as Well as Animals, Insects, Food, and Drugs (Issued in Final Form on January 4, 2017)

**Alan Sachs**, *Beveridge & Diamond, P.C.*

**2:30 p.m. – 2:45 p.m.**

**Break**

**2:45 p.m. – 3:15 p.m.**

**OSHA Compliance, Enforcement and Rulemakings**

- New Electronic Reporting Requirements and Anti-Retaliation Provisions Associated With the Recording and Reporting of Worker Injuries
- Recent Enforcement Trends
- Recent and Anticipated Rulemakings

**Jayni Lanham**, *Beveridge & Diamond, P.C.*

**3:15 p.m. – 3:30 p.m.**

**Closing Comments**

- Future Direction of the Roundtable
- Recommendations for Rebranding and Expansion
- Topics to Cover in 2017
- Next Meeting

**Betsy DuSold**, *Eli Lilly*